Original Article

Comparative evaluation of Air-Q blocker and Proseal laryngeal mask airway in patients undergoing elective surgery under general anaesthesia: A randomised controlled trial

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ABSTRACT

Background and Aims: The Air-Q blocker (Cook gas LLC, Mercury Medical, Clearwater, FL, USA) is a relatively new supraglottic airway device (SAD) with capability to serve as a conduit for intubation. As there is limited data on Air-Q blocker, the present study was performed to compare the efficacy of Air-Q blocker and Proseal laryngeal mask airway (PLMA) in patients undergoing elective surgery. **Methods:** A total of 90 American Society of Anesthesiologists (ASA) physical status I and II patients were randomly allocated to Air-Q blocker or PLMA group. Oropharyngeal leak pressure (OLP), insertion success, insertion time, ease of orogastric tube (OGT) insertion, fibreoptic visualisation of the glottis, haemodynamic and ventilation parameters, and complications at emergence and postoperatively were investigated. **Results:** OLPs were higher in PLMA group as compared to Air-Q blocker group ($P = 0.002$). Still, the OLP (27.5 ± 5.8 cm H_2O) was clinically effective in Air-Q blocker group.The mean time for successful insertion was significantly shorter for Air-Q blocker than PLMA ($P = 0.019$). The number of attempts to insert both the devices was comparable ($P \geq 0.05$). Air-Q blocker provided a significantly better fibreoptic score than PLMA ($P = 0.038$). The two groups were comparable in terms of ease of OGT insertion, haemodynamics and ventilation parameters, and complications at emergence and postoperatively. **Conclusions:** Air-Q blocker provides a clinically effective OLP though PLMA provides a slightly better sealing function in patients undergoing laparoscopic and non-laparoscopic surgeries under general anaesthesia requiring neuromuscular blockade. Air-Q blocker has shorter insertion time and a better fibreoptic view of glottis as compared to PLMA.

Key words: Air-Q blocker, general anaesthesia, laryngeal masks, proseal laryngeal mask airway

INTRODUCTION

A supraglottic airway device (SAD) requires lighter levels of anaesthesia and causes less haemodynamic upset, coughing, breath holding, sore throat, laryngospasm, and hypoxia, both during insertion and removal and a higher operation theatre turnover. Its role in the management of either anticipated or unanticipated difficult airway is highly recommended.[1,2] Proseal LMA (PLMA; Teleflex Medical Europe Ltd., Co Westmeath, Ireland) is an established reusable second-generation SAD with a high oropharyngeal leak pressure (OLP).[1]

The Air Q blocker (Cook gas LLC, Mercury Medical, Clearwater, FL, USA), developed by Dr. Daniel J Cook in 2004, is a relatively new polyvinyl chloride single-use

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SAD designed for system-wide use. It has a pre-curved shorter and wider airway tube for ventilation and conduit for intubation with standard endotracheal tubes (sizes 5.0–8.5). It has another specific integrated channel for placement of an orogastric tube (OGT) to suction, vent, and block the upper oesophagus. Its keyhole-shaped airway outlet without grill and elevation ramp directs the endotracheal tube in the midline and towards the laryngeal inlet.[1,3] It has been used successfully in the delivery of anaesthesia[4] and in the management of the difficult airway.[5]

So far, as per our knowledge, only two studies have compared Air-Q blocker with PLMA with differing results.[3,6] The primary objective of our study was to compare the OLP of Air-Q blocker and PLMA in patients undergoing elective surgery under general anaesthesia (GA). The secondary objectives were to compare both devices for device insertion success, ease of OGT placement, fibreoptic visualisation of the laryngeal inlet, haemodynamic and ventilatory parameters and perioperative pharyngolaryngeal complications if any.

METHODS

This prospective randomised controlled study was approved by the Institutional Ethics Committee and registered in Clinical Trial Registry of India. The study followed the principles of the 2013 Declaration of Helsinki. The study took place at a tertiary care hospital from May 2016 to May 2017. Ninety patients, aged 18–60 years, of either sex were included after obtaining informed consent. They had American Society of Anesthesiologists (ASA) physical status I or II. Patients with anticipated difficult airway (Airway Difficulty Score >8),[7] upper respiratory tract infection, increased risk of regurgitation and aspiration, body mass index (BMI) >35 kg/m^2, history of radiotherapy to the neck and pregnant patients were excluded.

Monitoring of basic physiological variables i.e., pulse oximetry, electrocardiography, heart rate, non invasive blood pressure, end-tidal carbon dioxide, and respiratory variables (compliance, resistance, minute ventilation, and peak airway pressures) using spirometry (Aespire View; GE Healthcare, Madison, WI, USA) was started before induction of anaesthesia. Standard anaesthesia plan for induction and maintenance was followed.

The patients were allocated to Air-Q blocker or PLMA group based on computer-generated randomisation table, and allotted concealment was ensured using an opaque sealed envelope by a technician not involved in the study. An experienced anaesthesiologist with at least 20 successful insertions of study devices conducted the study. Another anaesthesiologist recorded the data.

The size of SAD, based on the patient's weight,[8,9] and the insertion technique was in accordance with the manufacturer recommendations. After adequate preparation, Air-Q blocker was introduced with the digital method, and PLMA was introduced with a metal introducer. Both devices were advanced through the oropharynx and pushed back until resistance was met, and the introducer was removed in PLMA group. The cuff was inflated with air to an intra- cuff pressure of maximum 60 cm H_2O. Correct placement was identified by the bilateral rise of the chest wall, chest auscultation and end- tidal carbon dioxide waveform trace on the monitor.

The number of insertion attempts was recorded. Failure to insert SAD in two attempts was considered a failure. The time taken from facemask removal to the appearance of square wave capnography trace determined the time taken for insertion.

After SAD placement, an OGT was passed through the drain tube of both the devices with maximum two attempts, and aspiration of gastric contents or epigastric auscultation was used to confirm the correct placement of OGT. The flexible fibreoptic bronchoscope was passed through the airway tube, and anatomic position of SAD was determined using an established scoring system.[10]

After positioning and fixing the SAD, OLP was determined by transiently stopping ventilation and closing the adjustable pressure-limiting valve up to 30 cm H_2O with a fresh gas flow of 3 L/min. The OLP was the pressure in the circuit when the pressure manometer dial reached its stability.[11,12] Intermittent positive pressure ventilation was resumed after measurement of the OLP. Haemodynamic variables such as heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure were noted at baseline, after induction, just after device insertion and at 5, 10 and 15 minutes thereafter. Ventilation variables (peak airway pressure, minute ventilation and airway resistance) were also noted for the same period of time.

At extubation, the study SAD was inspected for the presence of visible blood. Post-operatively, the anaesthesiologist blinded to the allocation group assessed the patient for sore throat, dysphagia, and hoarseness at 0 hour, 2 and 24 hours thereafter.

Our sample size was based on the results of our pilot study where in OLP of Air-Q blocker came out to be 23 ± 5 cm H_2O. OLP of PLMA was 28 ± 6 cm H_2O based on a previous study.[13] With a difference of 5cm H_2O in OLP and a standard deviation of 6.0 cm H_2O, the sample size came out to be 38 patients per group at a power of 95% and confidence interval of 95%. We decided to include 20% extra patients to account for possible attrition; hence, 45 patients were recruited in each group.

Statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 22.0 for Windows). All quantitative variables were represented using measures of central location (mean, median) and measures of dispersion (standard deviation and standard error). Kolmogorov Smirnov tests were used to check the normality of quantitative data. For normally distributed measurable data (age and BMI), group means were compared using Student's t-test. Mann-Whitney test was applied for skewed data i.e., rest of demographic data, OLP, number of insertion attempts, insertion time, fibreoptic view, number of OGT insertion attempts, ease of OGT insertion and haemodynamic parameters. Frequencies and proportions were used to describe qualitative or categorical variables. Proportions were compared using the Chi-square or Fisher's exact test, depending on their applicability for the two groups. All the statistical tests were two-sided, and P value <0.05 was considered statistically significant.

RESULTS

Ninety patients meeting eligibility criteria were randomised into two groups of 45 each. In three patients (two patients in the Air-Q blocker and a patient in PLMA), the surgery proceeded with endotracheal intubation despite successful SAD placement, and these were excluded from analysis. Endotracheal intubation in these three patients had to be performed after removal of the SAD because of unanticipated difficult ventilation with high airway pressures. The data of 87 patients were subjected to analysis [Figure 1]. The statistical analysis revealed that the demographic profile of the patients was comparable between the two SAD groups [Table 1].

As shown in Table 2, the mean OLP was significantly lower in Air-Q blocker group than PLMA group [27.5 ± 5.8 cm H_2O and 31.9 ± 6.5 cm H_2O, respectively] ($P = 0.002$).

The first attempt success rate in patients with eventually successful SAD insertion was higher for PLMA 95.5% (42 out of 44) as compared to 90.7% (39 out of 43) in Air-Q blocker. The overall success rate in both groups was 100% in two attempts. The difference in the rate of successful placement of SAD was, however, statistically insignificant ($P = 0.434$). The maximum number of insertion attempts was limited to two to avoid undue trauma to the airway. Folding of the cuff tip in two cases made Air-Q blocker insertion difficult and required the second attempt. In another two cases, the second attempt with the smaller size Air-Q blocker was required due to the larger cup size with drain tube in relation to the oral cavity's inner volume, which posed difficulty in insertion.

Time to successful insertion of the Air-Q blocker was lesser and ranged from 10 to 28 s with a mean device insertion time of 16.4 ± 3.4 s, whereas that of PLMA ranged from 12 to 30 s with a mean device insertion time of 18.1 ± 3.3 s ($P = 0.019$). Fibreoptic scores were better for Air Q blocker as compared with PLMA ($P = 0.038$) [Table 3]. The ease of OGT placement was comparable for the two SADs [Table 2].

Table 1: Demographic data

	Group A Air- Q blocker (*n*=43)	Group P PLMA (*n*=44)	*P*
Age (years)	40.7±12.3	40.1±12.2	0.810
Sex (M/F), *n* (%)	6/37 (13.9%/86.1%)	6/38 (13.6%/86.4%)	0.966
ASA (I/II)	25/18 (58.1%/41.9%)	33/11 (75%/25%)	0.060
Weight (kg)	62.6±11.4	61.9±12.6	0.802
Height (cm)	157.1±5.2	157±5.9	0.923
BMI (kg/m^2)	25.3±4.2	25±4.4	0.763
Surgical time (min)	82±32	76±31	0.58
Anaesthesia time (min)	106±37	104±38	0.24

Values are expressed as mean±standard deviation or number of patients (%); ASA - American Society of Anesthesiologists; BMI - Body mass index

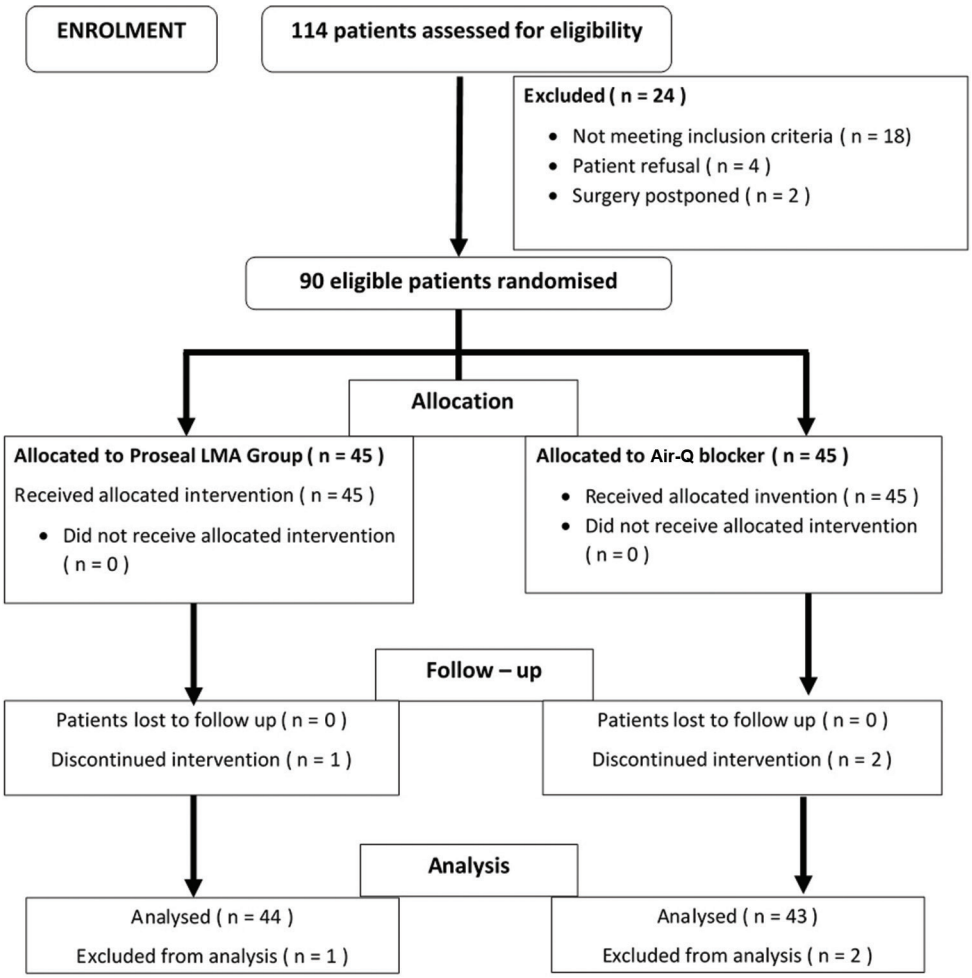

Figure 1: Consort Diagram

Table 2: SAD (Air-Q blocker and Proseal LMA) performance parameters

	Air-Q blocker Group A (*n*=43)	Proseal LMA Group P (*n*=44)	*P*
OLP (cm H2O)	27.5±5.8	31.9±6.5	0.002
Insertion Attempts			
1	39 (90.7%)	42 (95.5%)	0.434
2	4 (9.3%)	2 (4.5%)	
Insertion time (s)	16.4±3.4	18.1±3.3	0.019
Ease of OGT insertion			0.055
Easy	39 (90.7%)	44 (100%)	
Difficult	4 (9.3%)	0	
Impossible to insert	0	0	
Blood stain on device			
Yes	1 (2.3%)	2 (4.5%)	1.00
No	42 (97.7%)	42 (95.5%)	
Postoperative (0,2,24 h)			
Sore throat	3,1,0 (6.9,2.32%, 0)	4,2,0 (9.1, 4.5%, 0)	1.000/1.000/-
Dysphagia	1,0,0 (2.3%, 0,0)	1,0,0 (2.3%, 0,0)	1.000/-/-
Hoarseness	-	-	-

Values are presented as Mean±Standard Deviation or number (%); LMA - Laryngeal mask airway; OLP - Oropharyngeal leak pressure; OGT - Orogastric tube

In our study, no significant statistical difference was found in the two groups in terms of haemodynamics and ventilation parameters. However, the difference in airway compliance 15 min after device insertion showed statistical significance ($P < 0.05$) [Figure 2].

Table 3: Fibreoptic scoring system involving a four-point assessment of the view of the vocal cords and epiglottis

Score	Air-Q blocker *n* (%)	PLMA *n* (%)	*P*
4, only vocal cords visible	27 (62.8%)	17 (38.6%)	0.038
3, vocal cords plus posterior epiglottis visible	12 (27.9%)	21 (47.7%)	
2, vocal cords plus anterior epiglottis visible	2 (4.7%)	4 (9.1%)	
1, vocal cords not visible	2 (4.6%)	2 (4.5%)	

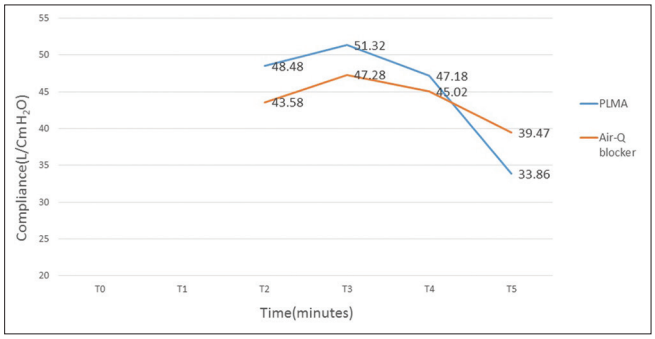

Figure 2: Airway compliance measured after device insertion at 5, 10, 15 min in PLMA and Air-Q blocker groups

At emergence, 2.3% of patients in Air-Q blocker group and 4.5% of patients in PLMA group had a blood-stained device on removal. Three patients in the Air-Q blocker and four patients in PLMA group complained of sore throat at 0 hours postoperatively. After 2 hours in post anaesthesia care unit (PACU), one patient in Air-Q blocker group and two patients in PLMA group had sore throat, but this difference was not significant [Table 2].

DISCUSSION

The results of our study demonstrate a significantly higher OLP with PLMA than with the Air-Q blocker. However, the Air-Q blocker provided a significantly shorter mean time for successful insertion and a significantly better fibreoptic view of vocal cords than the PLMA.

In the present study, PLMA provided higher values of OLP than Air-Q blocker probably due to the larger ventral cuff of PLMA that secures the proximal pharynx and the dorsal cuff, which pushes the ventral cuff more thoroughly into the periglottic tissues. Our results corroborate with the study of Youssef *et al.* wherein OLP in PLMA was higher as compared to Air-Q blocker (23.7 ± 1.5 versus 22.4 ± 1.3 cm H_2O, respectively).[6] On the contrary, Gupta *et al.* found higher OLP in Air-Q blocker compared to PLMA in a study on healthy adults undergoing laparoscopic cholecystectomy (31.5 ± 2.4 versus 29.4 ± 2.1 cm H_2O, respectively).[3] Brimacombe *et al.* stated that any SAD providing higher OLP than 10 cmH_2O can be deemed safe enough.[14] In our study, OLP of Air-Q blocker was well within the acceptable clinical range. Thus, Air-Q blocker can provide protection against aspiration and be used for positive pressure ventilation.

In our study, the first attempt success rate for Air-Q blocker was 90.7%, which was comparable to the study by Attarde *et al.* (88.3%), but that for PLMA was higher (95.5%) similar to a study by Tham *et al.* (97%).[15,16]

The shorter mean device insertion time for Air-Q blocker in the present study as compared to PLMA (16.4 ± 3.4 versus 18.1 ± 3.3 s, respectively) could be due to its hyper-curved airway tube that makes it more flexible and could affect subjective ease of placement. The removal of the dedicated metal introducer in PLMA before cuff inflation adds an extra step. Youssef *et al.* also reported shorter insertion time for Air-Q blocker as compared to PLMA (18.4 ± 3.8 s versus 23.4 ± 3.5s, respectively).[6] Contrary to this, Gupta R *et al.* found that Air-Q blocker had a longer insertion time than PLMA (25.6 ± 5.7 and 18.7 ± 3.2 s, respectively) due to easy gastric tube–guided insertion of PLMA.[3]

In our study, PLMA group had 100% first attempt success rate of OGT insertion, whereas in Air-Q blocker group, it was 90.7%. The low first attempt success rate in Air- Q blocker was probably due to coiling of OGT after crossing distal end of the drain tube in the peripharyngeal tissues.[17] Our results are supported by Gupta *et al.* and Brimacombe *et al.* in which OGT placement in PLMA group was 100%.[3,18] OGT insertion rate in Air-Q blocker in our study closely coincides with the results of the study of Gupta *et al.* and Youssef *et al.* in which the success rate was 86.4% and 93.3%, respectively.[3,6]

Fibreoptic scoring is used to evaluate the anatomical positioning of the SAD. It has been shown that the higher grades correlate to an improved seal, reduced work of breathing, and easier intubation.[10] In our study, the Air-Q blocker gave more favourable fibreoptic views compared to PLMA. This could be attributed to the absence of grill at its ventilating orifice

and to the elevation ramp that elevates epiglottis and centres the larynx, maximising space of tracheal tube and breathing conduit. The presence of a hole on top of the keyhole at the distal end prevents epiglottis from getting suctioned into it, thus improving airway alignment. The inferior fibreoptic views in PLMA may be due to the narrower airway tube and epiglottis down-folding. Despite this variation, the two devices provided satisfactory ventilation without the requirement of any further airway manipulations.

In our study, no significant statistical difference was found in the two groups in terms of haemodynamics. The ventilation parameters play an important role in determining whether a SAD can be used for surgeries that require increased pressures like laparoscopic surgeries. In our study, no critical factual distinctions in the ventilatory parameters were found except in compliance at 15 min of device insertion, due to creation of pneumoperitoneum in some laparoscopic surgeries within 15 min of device insertion.

In our study, a blood-stained device was noted in 2.3% (1/42) patients in Air-Q blocker group and 4.5% (2/42) patients in PLMA, similar to Gupta *et al.* findings (Air-Q blocker 4/36 and 2/42 in PLMA group).[3] Incongruently, Youssef *et al.* reported a higher incidence of 10% in Air-Q blocker and 13.3% in PLMA with blood on the device.[6]

In our study, the two groups were comparable for postoperative complications. Galgon *et al.* observed that a greater number of patients had sore throat in Air-Q ILA compared to PLMA, probably due to cuff hyperinflation leading to mucosal injury.[19] Gupta *et al.* also reported a higher incidence of sore throat in Air-Q blocker due to its longer time for insertion, more attempts, and less ease of insertion.

There are a few limitations of our study. Firstly, we studied the use of SADs in healthy young adults in elective cases, so the results may not be generalised to patients with poor lung compliance, elderly, obese patients, and in emergency scenarios. Also, the primary investigator involved was not blinded to the type of SAD used adding a source of possible bias. To abate it, the postoperative outcome assessor and the patients were blinded to the group assignment. Thirdly, as SAD insertion was done using a muscle relaxant, the results may not be the same for patients without muscle relaxation. Fourth, OLP was not measured in trendelenburg/lithotomy or with extreme neck positions[20,21] and at different times during surgery.[22,23] To define a future place of Air-Q blocker in the armamentarium of SADs, studies in different clinical situations especially in emergencies, need to be carried out. A better fibreoptic view of vocal cords could make Air-Q blocker a good option as a conduit for tracheal intubation, if required in emergency scenarios.

CONCLUSION

Air-Q blocker has a clinically effective OLP with shorter insertion time as compared to PLMA in patients undergoing laparoscopic and non-laparoscopic surgeries under GA using neuromuscular blockade.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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